Monoclonal Antibodies for COVID-19: The Clinical Evidence

Monoclonal antibodies are laboratory-produced proteins that act as substitute antibodies to restore, enhance, or mimic the immune system's attack on cells. Given the novel nature of SARS-CoV-2, the virus that causes COVID-19, the science is evolving rapidly. This fact sheet provides the latest clinical evidence available.

CLINICAL TRIALS AND FDA EMERGENCY USE AUTHORIZATIONS (EUA)

As of March 29, 2021, the following monoclonal antibodies have been authorized by the FDA for emergency use:

- **REGEN-COV (casirivimab and imdevimab)[1]**
- **Bamlanivimab and etesevimab[2]**
- **Bamlanivimab[3]**

Note: Although bamlanivimab ***alone*** is currently authorized for emergency use, the U.S. Government, in coordination with Eli Lilly and Company, stopped distribution of bamlanivimab on March 24, 2021 due to the sustained increase in bamlanivimab-resistant variants of SARS-CoV-2 in the U.S.[4] The NIH COVID-19 Treatment Guidelines Panel "recommends against the use of bamlanivimab monotherapy [...] If combination products are not available, the use of bamlanivimab monotherapy can be considered for people who meet the EUA criteria on a case-by-case basis."[5]

REGEN-COV (Casirivimab and Imdevimab)[1]:

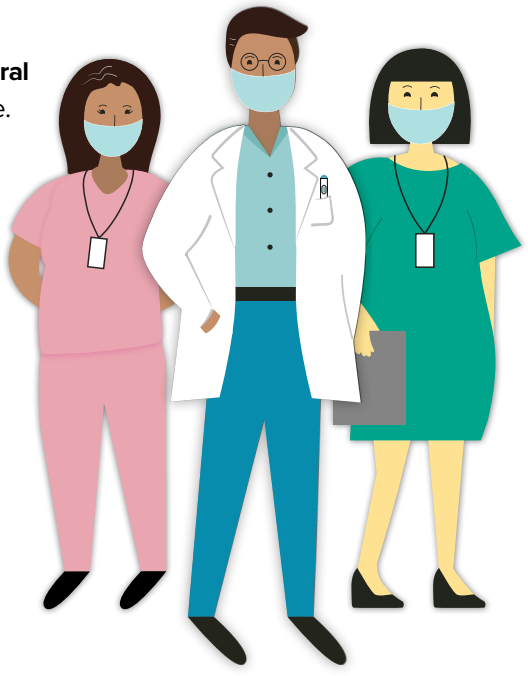
Reduced Viral Loads, ER Visits, and Hospitalizations

"The **largest reductions in viral load** relative to **placebo occurred in patients with high viral load** (-0.78 log10 copies/mL) or who were seronegative (-0.69 log10 copies/mL) at baseline. Reductions occurring from Day 1 through Day 11 were similar to those for Day 1 through Day 7."[6]

— FDA EUA CDER Scientific Review Document (November 21, 2020): Phase 1 and 2 data from an ongoing trial R10933-10987-COV-2067; data from 799 symptomatic patients.

"When considering only individuals at high risk for progression to severe disease, [...] **hospitalization or emergency room visits were reported in 9% of participants in the placebo group compared to 3% in the combined casirivimab and imdevimab dose groups**"[6] – a 70% relative reduction.

— FDA EUA CDER Scientific Review Document (November 21, 2020): Phase 1 and 2 data from an ongoing trial R10933-10987-COV-2067; data from 799 symptomatic patients.



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Bamlanivimab and Etesevimab[2]:

Reduced ER Visits, Hospitalizations, and Deaths

"[...] **COVID-19 related hospitalization or death [...] occurred in 36 subjects treated with placebo (7%) as compared to 11 events in subjects treated with bamlanivimab 2,800 mg and etesevimab 2,800 mg together (2%)**, a 70% [relative] reduction. **There were 10 deaths in subjects treated with placebo and no deaths in subjects treated with bamlanivimab 2,800 mg and etesevimab 2,800 mg together**."[7]

— *FDA EUA CDER Scientific Review Document (February 9, 2021): Phase 3 data from BLAZE-1 trial; total of 1035 participants at high risk for progression to severe COVID-19 disease were enrolled in Treatment Arms 7-8 (efficacy results).*

Bamlanivimab[3]:

Reduced ER Visits and Hospitalizations

"When considering only individuals at high risk for progression to severe disease, hospitalization or emergency room visits were reported in 10% of subjects in placebo vs 2% in the 700 mg group reported [...]."[8]

— *FDA EUA CDER Scientific Review Document (November 9, 2020): Phase 2 data from Trial J2W-MC-PYAB, BLAZE-1 trial; total of 465 ambulatory (non-hospitalized) subjects with COVID-19.*

For more information, visit

CombatCOVID.hhs.gov

English: 1-877-332-6585 • Spanish: 1-877-366-0310

References

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